APPENDIX A: CONTENT OF EDUCATION PROGRAM

The training for prescribers required by the elements to assure safe use must contain the following content:

1. General information for safe opioid prescribing
    a. Patient selection and assessment
        i. Determine goal of therapy
        ii. Assessment of the risk of abuse, including history of substance abuse and serious mental illness
        iii. When relevant, determining if patient is opioid tolerant
    b. Considerations when prescribing opioids
        i. Pharmacokinetics and potential for overdose
        ii. Addiction, abuse, and misuse
        iii. Intentional abuse by patient or household contacts
        iv. Interactions with other medications/substances
    c. Managing patients taking opioids
        i. Establishing goals for treatment and evaluating pain control
        ii. Use of Patient Provider Agreements (PPAs)
        iii. Adherence to a treatment plan
        iv. Recognizing aberrant behavior
        v. Managing adverse events
    d. Initiating and modifying dosing of opioids for chronic pain
        i. As first opioid
        ii. Converting from one opioid to another
            1. Converting from immediate-release to extended-release and long-acting products
            2. Converting from one extended-release and long-acting product to another
        iii. Titrating to effect/tolerability
        iv. How to deal with missed doses
    e. Maintenance
        i. Reassessment over time

ii. Tolerance

f. Monitoring patients for misuse and abuse

i. Utilization of prescription monitoring programs to identify potential abuse

ii. Understanding the role of drug testing

iii. Screening and referral for substance abuse treatment

g. How to discontinue opioid therapy when it is not needed any longer

2. Product Specific Information

a. Pharmacokinetic characteristics

b. Product specific toxicity

c. Requirements for opioid tolerance for certain long-acting and extended-release products

d. Individual product information modules

i. Fentanyl transdermal system

ii. Hydromorphone ER

iii. Methadone (For the treatment of moderate to severe pain not responsive to non-narcotic analgesics)

iv. Morphine ER

v. Oxycodone ER

vi. Oxymorphone ER

vii. Buprenorphine (for the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time)

viii. New products

3. Patient counseling

a. Information about prescribed opioid

b. How to take opioid properly

i. Adherence to dosing regimen

ii. Risk from breaking, chewing, crushing certain products

c. Reporting adverse effects

d. Concomitant use of other CNS depressants, alcohol, or illegal drugs

e. Discontinuation of opioid

f. Risks associated with sharing, i.e., overdose prevention
g. Proper storage in the household
    i. Avoiding accidental exposure
h. Avoiding unsafe exposure by preventing theft and proper disposal
i. Purpose and content of Patient Provider Agreement

APPENDIX B: PATIENT EDUCATION

Materials to provide to patients as part of patient counseling must include:

1. How to take opioid properly
    a. Adherence to dosing regimen
    b. Risk from breaking, chewing, crushing certain products
    c. Symptoms of overdose
2. Reporting adverse effects
3. Concomitant use of other CNS depressants, alcohol, or illegal drugs
4. Discontinuation of opioid
5. Risks associated with sharing
6. Proper storage in the household
    a. Avoiding accidental exposure
7. Avoiding unsafe exposure by preventing theft and proper disposal
8. Purpose and content of Patient Treatment Agreement
9. Links to Web sites with more information about topics 1 through 8

APPENDIX C: REMS TEMPLATE

Initial REMS Approval: XX/XXXX
Most Recent Modification: XX/XXXX

Application number TRADE NAME (DRUG NAME)

Class of Product as per label

Applicant name

Address

Contact Information

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

Reduce serious adverse outcomes resulting from inappropriate prescribing, misuse and abuse of extended-release (ER) and long-acting (LA) opioids while maintaining patient access to pain medications. Adverse outcomes of concern include addiction, unintentional overdose, and death.

II. REMS ELEMENTS:

A. Medication Guide or PPI

A Medication Guide will be dispensed with each [drug name] prescription. [Describe in detail how you will comply with 21 CFR 208.24.]

B. Communication Plan

A communication plan is not required.

C. Elements To Assure Safe Use

1. The sponsor must ensure that training is provided to prescribers who prescribe DRUG. An outline of the content for this information is described in Appendix A. The training must include successful completion of a knowledge assessment and proof of successful program completion. To assure access to DRUG and minimize the burden on the healthcare delivery system, FDA expects that the training will be conducted by accredited, independent continuing medical education (CME) providers, to the extent practicable.

2. The sponsor must provide to prescribers information that the prescriber can use to educate patients in the safe use, storage, and disposal of opioids. An outline of the content for this information is described in Appendix B.

3. The sponsor must inform prescribers of the existence of the REMS and the need to successfully complete the necessary training.

D. Implementation Plan

An implementation plan is not required.

E. Timetable for Submission of Assessments

COMPANY will submit REMS Assessments to the FDA no less frequent than 6 months, 12 months, and annually after the REMS is initially approved from the date of approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. COMPANY will submit each assessment so that it will be received by the FDA on or before the due date.